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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Atlanta District Office
60 Eighth Street N.E.
Atlanta, GA 30309

Telephone: 404-253-1161
FAX: 404-253-1202

December 3, 2003

VIA FEDERAL EXPRESS

John F. Kral, President
Kral X-Ray, Inc.
3145 Friendship Rd.
Buford, GA 30519

Warning Letter
(04-ATL-4)

Dear Mr. Kral:

During an inspection of your firm located at 3145 Friendship Rd., Buford, GA conducted on 7/30-8/1/03, FDA determined that your firm is an assembler of diagnostic x-ray equipment. At that time, our investigator explained to you your responsibility to file a Report of Assembly of a Diagnostic X-Ray System, Form FDA-2579, for each certified diagnostic x-ray system you assemble (see attached copy of applicable regulations). We have identified the following facilities for which your assembly was not reported to FDA in accordance with 21 CFR 1020.30:

1. [redacted]
2. [redacted]
3. [redacted]
4. [redacted]
5. [redacted]
6. [redacted]
7. [redacted]
8. [redacted]
9. [redacted]
10. [redacted]
11. [redacted]
12. [redacted]
13. [redacted]
14. [redacted]
15. [redacted]
16. [redacted]
17. [redacted]
18. [redacted]
19. [redacted]
20. [redacted]
21. [redacted]

The above installations may not be all inclusive list of all the systems you installed without submitting a Report of Assembly. You should review your installation records, invoices, etc. to determine all the

installations which were made by you during the past five years. We request that you provide evidence that the above installations, as well as the installations which you identify through your review of records, are in compliance with applicable portions of the Performance Standard for Diagnostic X-Ray Equipment (Title 21, Code of Federal Regulations (CFR), Sections 1020.30-32 (copy enclosed)).

Accurate and complete Reports of Assembly of a Diagnostic X-Ray System, Form FDA-2579, are required to be submitted to FDA, the appropriate State Radiation Control Program, and the purchaser within 15 days following the completion of assembly pursuant to 21 CFR 1020.30. As part of your required corrective action under 21 CFR 1004, within 15 days you must complete Form FDA-2579 and submit copies to the above indicated individuals for each installation listed above and any additional installation you discover in your review of records. Failure to file a Report of Assembly of a Diagnostic X-Ray System, Form FDA-2579, is a violation of the Federal Food, Drug, and Cosmetic Act (the Act), Section 538 of Subchapter C-Electronic Product Radiation Control (formerly the Radiation Control for Health and Safety Act of 1968).

We field tested nine of the above installations and determined that 3 out of the 9 installations failed to comply with the Performance Standard for Diagnostic X-Ray Systems and Their Major Components (Performance Standard). We have separately sent you notification letters for the 3 non-compliant installations for which corrections have been requested.

Failure to promptly correct the above violations can result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include seizure and/or injunction and/or the imposition of civil penalties. Persons violating Section 538 of the Act are subject to civil penalties up to $1,000 per violation and up to a maximum of $300,000.

In addition to providing a Form FDA-2579 for each of the above listed installations, you should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Your response should be sent to Serene N. Ackall, Compliance Officer at the address in the letterhead. If you have any questions, you may contact Ms. Ackall at 404-253-1296.

Sincerely,

Mary Woleske

Mary Woleske, Director
Atlanta District

Enclosures